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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/781,021 | 02/18/2004 | James D. Ralph | F-200 CON 1 | 2824 |
| 51640 | 7590 | 03/22/2006 | EXAMINER | |
| SPINE MP LERNER, DAVID, et al. 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090 | | | PELLEGRINO, BRIAN E | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3738 | |

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------|------------------------------|--|
| Office Action Summary | Application No. 10/781,021 | Applicant(s) RALPH ET AL. | |
| | Examiner Brian E Pellegrino | Art Unit 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>8/22/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The following Office Action contains rejections to previously allowed and/or previously objected-to-as-allowable material as indicated in Office Action mailed 8/22/05. Accordingly, the following action has been made Non-Final.

Information Disclosure Statement

The Harrington '889 reference is not considered in the filed IDS on 8/22/05, since the Examiner already cited the reference in the Final rejection.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "annular groove in the retaining wall" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be

labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the "annular groove in the retaining wall" is not found in the written disclosure.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,2,4,7,8,10,11 are rejected under 35 U.S.C. 102(b) as being anticipated by Harrington (5893889). Fig. 2 shows an artificial intervertebral spacer device with a first plate member 32 and a second plate member 34. It can also be seen that the second plate surfaces (36, 40 respectively) face away from one another. Additionally, it can be seen that the second plate has a convex element 54 mounted thereon with a curvate volume 50 coupled together with the first member by retaining wall 78 and retaining ring 74. It can additionally be seen the retaining ring extends from an annular groove 70 in the retaining wall. With respect to claim 4, it can also be seen that the second plate member comprises a post structure 45 with a ball 46 extending from the second plate. It can be construed that the retaining wall is indirectly in contact with the first plate member and extends outward from the plate. It is also noted that the wall and rings limit the movement of the convex

element once the entire device is assembled. The convex element is axially movable relative to the first plate **when assembling** the components to form the implant. The use of “substantially enclosed area over said first plate surface” is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited. It can be construed that the wall and ring clearly define an area that “substantially enclose an area” over the first plate surface.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3,5,6,9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrington '889 in view of Ralph et al. (5989291). Harrington is explained supra. However, Harrington fails to disclose the convex element is a Belleville washer or the post includes a threaded bore to receive a set screw or that the first plate has an outer perimeter where its diameter is larger than the retaining wall diameter. Ralph et al. teach (Fig. 9) an intervertebral spacer device having a Belleville washer 230 between two plates with a post and ball coupled to the washer and also secured with a setscrew 205. Ralph also teaches that the Belleville washer is one of the strongest configurations for a spring, col. 3, lines 58-62. Ralph additionally teaches the setscrew locks the post in place, col. 4, lines 44-46. It would have been obvious to one of ordinary skill in the art to substitute a Belleville washer for the convex element and also incorporate a set screw as taught by Ralph et al. with the spacer device of Harrington such that it provides a stronger force restoring subassembly than a shock absorber. It would have been an obvious matter of design choice to modify the dimensions of the diameters of the plate members and the retaining wall, since applicant has not disclosed that using a plate

Art Unit: 3738

member with a larger diameter than the retaining wall provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the dimensions of the device taught by Harrington or the claimed larger diameter plate in claim(s) 9 because both spinal implants perform the same function of providing a pivot moving spinal spacer.

Response to Arguments

After further review, it is the Examiner's position that the claims do not clearly set forth what is meant by the convex element being movable or the location of the retaining wall or ring to distinguish over Harrington.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8,10,11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,3,6-9 of U.S. Patent No. 6918934 in view of Harrington '889. US patent claims the same invention except for the annular groove in a retaining wall. Harrington teaches an "annular groove" in a "retaining wall" of the device. It would have

been obvious to one of ordinary skill in the art to incorporate an "annular groove" in the retaining wall such that it prevents the ring from moving out of place.

Claims 1-8,10,11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,2,7 of U.S. Patent No. 6740117 in view of Harrington '889. US patent claims the same invention except for the annular groove in a retaining wall. Harrington teaches an "annular groove" in a "retaining wall" of the device. It would have been obvious to one of ordinary skill in the art to incorporate an "annular groove" in the retaining wall such that it prevents the ring from moving out of place.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Thursday from 8am to 5:30pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

